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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,695	09/30/2003	Robin D. Pierce	ADCI-073	5085

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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1724	

MAIL DATE	DELIVERY MODE
04/27/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,695	PIERCE ET AL.	
	Examiner	Art Unit	
	KAJ K. OLSEN	1724	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,8-16,18,21 and 23-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,8-16,18,21 and 23-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/16/2011;2/23/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The examiner has withdrawn the outstanding rejections under 35 U.S.C. 112, first paragraph, in view of the amendment of claims 1, 16, and 31 and the arguments concerning claim 35.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3, 6, 8-11, 29, 31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (USP 6,103,033) in view of any one or more of Charlton et al (USP 5,798,031), Maley et al (USP 5,770,028), and/or Hoenes et al (USP 5,122,244) with evidence from Ikeda (5,582,697).

4. Say discloses a biosensor for determining a concentration of an analyte in a liquid sample (e.g. glucose in blood) comprising an electrode support 50, an arrangement of electrodes (58, 60, 62) disposed on the electrode support, the arrangement of electrodes comprising at least one working electrode 58 and a second electrode (60, 62), the working electrode comprising conductive ink and at least one enzyme and mediator in it. See col. 20, ll. 10-29 where Say teaches placing the catalyst in the electrode ink and see col. 19, l. 43 - col. 20, l. 9 where Say considers the mediator to be part of the catalyst as well. Say discloses first and second conductive tracks 52 leading from the working and second electrode to an electrical contact 49. See fig. 11 for example. Say also discloses that the two electrodes can be separated by less than

about 200 microns (col. 11, ll. 22-36). Say does not explicitly disclose the use of a polymer that provides a hydrophilic domain. Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Say would inherently create hydrophilic domains in the conductive ink. In addition, Hoenes discloses an alternate electrode containing both conductive particles and enzymes (like say) and teaches that the electrode should contain a small amount of hydroxyethyl cellulose, which is a polymer having hydrophilic domains (col. 19, ll. 17-27). Maley is drawn to an alternate measuring electrode comprising a mixture of conductive particles and enzymes (like Say) and teaches that it is desirable to add a surfactant material to the electrode in order to facilitate wetting of the electrode. See col. 15, ll. 22-63. A surfactant having a high hydrophilic lipophilic balance (HLB) that facilitate aqueous sample uptake inherently provides hydrophilic domains. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of either Hoenes or Maley for the biosensor of Say so as to facilitate the wicking up of sample to the electrode. As to Maley applying its surfactant after the electrode is dry (as opposed to in the conductive ink itself), applicant evidences that the eventually electrode will be dried prior to use of the electrode anyway (p. 22, ll. 27 and 28). Hence, whether or not the hydrophilic domains are provided to the ink itself or after the ink has dried would not alter the prepared biosensor having a dried ink containing hydrophilic domains.

5. With respect to the new limitation requiring the polymer being present in "about 1% by weight", finding the appropriate amount of hydrophilic polymer or surfactant that provides the desired level of wetting, including the use of about 1% by weight, would have required only routine skill in the art. Moreover, Hoenes appears to teach that only a small amount of hydrophilic polymer is necessary for inducing the desired hydrophilic domains for the electrode (col. 19, ll. 17-27). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize about 1% of the polyethylene glycol or surfactant of Charlton or Maley as suggested by Hoenes because only a small amount of hydrophilic material is necessary for improving the sensor wetting properties.

6. With respect to the mediator composition, the osmium complexes of col. 19, ll. 12-33 of Say for example read on the defined organometallic and organic compounds of the claims.

7. With respect to the use of small sample volumes, see Say, col. 4, ll. 8-14.

8. With respect to the electrode area, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize electrode areas of from 0.5 mm^2 to 5 mm^2, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. In particular, larger electrodes would provide greater sensitivity while smaller electrodes would hold the overall size of the sensor down. Finding the appropriate area that balances these competing concerns requires only routine skill in the art.

9. With respect to the presence of a third or trigger electrode, Say discloses a third electrode 62 (col. 14, ll. 44-50) and this would read on the defined third electrode. Although not disclosed as being a trigger electrode, the term "trigger" merely defines how applicant intends to utilize the

electrode and does not further define the structure of the electrode itself. This is evidenced by Ikeda where a given reference electrode for the sensor can be utilized as a trigger electrode as well (col. 8, ll. 29-37) indicating that triggering is just the intended use of the electrode and doesn't further define it.

10. With respect to the set forth fourth electrode, see Say fig. 6 and col. 14, ll. 29-43. With respect to the electrode having a trigger function, this again defines how the electrode is to be used and doesn't further define the structure of the electrode itself. See the discussion of Ikeda above.

11. With respect to the use of dehydrogenase, see Say col. 19, ll. 43-55.

12. With respect to claim 31 (those limitations not covered above), Say discloses that the biosensor can be made to contact a meter (i.e. control unit). See col. 13, ll. 28-40.

13. With respect to claim 35 (those limitations not covered above), because the hydrophilic polymer and enzyme are separately provided and provide differing function for the electrode, using differing amounts of each of the enzyme and polymer to tailor the electrodes sensitivity and fluid wetting ability would have required only routine skill in the art. As to the use of more enzyme than polymer, Hoenes teaches that only a small percentage of hydrophilic polymer is necessary for successful wetup (col. 19, ll. 17-27), so it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an amount of the polymer of Charlton or Maley less than the amount of enzyme because very little polymer appears to be necessary for successful electrode wetup.

14. Claims 1, 3, 6, 8-16, 18, 21, 23-31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and any of Charlton, Maley, and/or Hoenes and with evidence from Ikeda.

15. Feldman discloses a biosensor (col. 1, ll. 13-14) having: an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and at least one reagent incorporated in the working electrode (col. 21 , ll. 28- 31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38). Feldman does not disclose placing the enzyme and the mediator into a conductive ink. Say (who has the same assignee as Feldman) discloses that in an effort to minimize leaching of the catalysts (i.e. the enzyme and mediator), the catalysts can be incorporated directly into the conductive ink of the sensor. See col. 19, l. 56 - col. 20, l. 29, especially col. 20, ll. 10-29. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Say for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode as well as keeping the enzyme from leaching away. Keeping the mediator and enzyme from leaching away was a particular concern of Feldman (see

abstract for example) and the suggestion of incorporating the enzyme and mediator into the conductive ink by Say represents an alternate or additional way to prevent such a leaching from occurring.

16. Neither Feldman nor Say explicitly discloses the use of a polymer that provides hydrophilic domains in the conductive ink. Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. Moreover, both Maley and Hoenes render obvious the addition of a polymer having hydrophilic domains to an electrode in order facilitate the wetting up of the electrode. See Maley col. 15, ll. 22-63 and Hoenes col. 19, ll. 17-27. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of any of Charlton, Maley, or Hoenes for the sensor of Feldman and Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Feldman and Say would inherently create hydrophilic domains in the conductive ink.

17. With respect to the various dependent claims, see the discussion of Feldman from the previous 10/8/2009 office action and of Say and Ikeda above.

18. Claims 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say in view of any of Charlton, Maley, or Hoenes as set forth for claims 1 and 31 above, and in further view of Yamashita et al (USP 5,472,590).

19. Say and any of Charlton, Maley, or Hoenes set forth all the limitations of claims 32 and 34, but did not explicitly recite the use of polyethylene glycol as the hydrophilic polymer.

However, polyethylene glycol is a subset of the broader polymer class of polyethylene oxide utilized by Charlton. In particular, polyethylene glycol is polyethylene oxide where the terminal groups of the polymer are hydroxyl units. Yamashita explicitly teaches that polyethylene glycol is a particular useful choice of polyalkylene oxide polymer when the property being desired is a hydratable substance (i.e. "water-keeping property"). See abstract and col. 5, ll. 51-63 of Yamashita. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the polyethylene glycol as taught by Yamashita for the polyethylene oxide suggested by Charlton, for the surfactant of Maley, or the hydrophilic polymer of Hoenes for the biosensor of Say and Charlton because polyethylene glycol has been demonstrated as being a suitable choice of hydratable polymer for sensor applications.

20. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and any of Charlton, Maley, or Hoenes as set forth for claims 1, 16, and 31 above, and in further view of Yamashita.

21. These claims are further rejected over Yamashita for the reasons set forth above.

Response to Arguments

22. Applicant's arguments filed 2/23/2011 have been fully considered but they are not persuasive, except for the arguments concerning the 112, first paragraph rejection of claim 35. With respect to the remaining arguments, applicant merely reiterates the applicant's objections to the use of Charlton and appears to concentrate on the new teaching of Hoenes. The examiner has addressed the arguments concerning Charlton previously (see for example par. 39-42 from the 2/2/2009 office action). With respect to the new teaching of Hoenes, applicant suggests that

Hoenes teaches away from the claimed "about 1% by weight" because Hoenes teaches the use of 4% by weight ethylene glycol. As an initial point, the examiner would like to emphasize that the examiner was not relying solely on the teaching of Hoenes for this limitation concerning the concentration. See the first sentence of par. 9 from the 8/16/2010 office action (reprinted above). Finding the appropriate level of hydrophilic polymer to control the desired level of electrode wetting requires only routine skill in the art with or without the suggestion of Hoenes. However addressing the issues related to Hoenes, it appears that applicant has misconstrued the rejection. The hydrophilic polymer of Hoenes is not the ethylene glycol (which isn't even a polymer), but the hydroxyethyl cellulose which is a well known hydrophilic polymer (Hoenes calls the solution containing the polymer a "swelling mixture" (i.e. wetting mixture)). The hydroxylethyl cellulose is only present at 2% by weight in this solution that the other electrode components are eventually added to. Hence, the eventual hydrophilic polymer concentration of Hoenes would presumably be less than 2% by weight. Moreover, the examiner was never relying on Hoenes for exact concentrations of hydrophilic polymer, but only that the amount of hydrophilic material necessary for the electrode need only be very small to provide the desired sensor wetting properties (last sentence of par. 9 from the 8/16/2010 office action). Whether or not the examiner was relying on the suggestion of either 2% or 4% from Hoenes, the issue would not have been whether 2% or 4% read on "about 1%", but whether or not the 2% or 4% rendered obvious the use of very small amounts of hydrophilic material. Both 2% and 4% are very small percentages and are very close and arguably overlapping the now claimed "about 1%". Hence Hoenes suggests only very small amount of hydrophilic material are necessary for the electrode

to provide wetting capability. There is nothing critical or unexpected disclosed about applicant's "about 1%" and there is nothing suggested as being critical about the use of the 2% for Hoenes.

23. Applicant's remaining arguments concerning the further use of Feldman, Ikeda, or Yamashita appear to rely on the perceived failings of the earlier use of Charlton and Hoenes. Because the examiner was not persuaded by the various arguments concerning Charlton (the various previous office actions) and was not persuaded by the new arguments concerning Hoenes (see above), these further arguments are similarly not persuasive.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith D. Hendricks can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1724

April 24, 2011